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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,844	08/25/2003	Subramaniam C. Krishnan	30909-1	3856
24256	7590	10/12/2006	EXAMINER	
DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			MALAMUD, DEBORAH LESLIE	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/648,844	Applicant(s) KRISHNAN, SUBRAMANIAM C.	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12-16, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-10, 12-16 and 19-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 24 July 2006.
2. Applicant's election with traverse of group III (claims 11 and 17-18) in the reply filed on 24 July 2006 is acknowledged. The traversal is on the ground(s) that the applicant believes that it would not be unreasonably burdensome for the examiner to consider all of the claims as originally filed. This is not found persuasive because groups I-IV relate to different inventions, and are differently classified. The subject matters these claim groups relate to are patentably distinct. The requirement is still deemed proper and is therefore made FINAL.

Drawings

3. The drawings are objected to because of minor informalities; see the attached PTO-948. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 5, the claim states, "the catheter *may* be inserted;" in line 6, the claim states, "a transseptal needle *may* be urged through;" and in lines 8-9, the claim states, "the distal end of the catheter *can* be used." These statements are vague and do not positively recite the subject matter the applicant is intending the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Svenson et al (U.S. 5,409,008). Svenson discloses, (col. 2, lines 30-36) "a mapping catheter which includes a polymer member, bipolar sensing electrodes placed on a distal end of said polymer member, a spaced unipolar electrode at a spaced distance from said bipolar electrodes, and a lumen within said polymer member for the passage of a laser catheter or other instrument." Svenson further discloses, (col. 3, lines 13-17) "a laser delivery catheter can be passed through the center hollow lumen of the mapping catheter and the myocardium irradiated for a predetermined period of time to ablate the site." The examiner considers this to be a hollow lumen, a first electrode positioned on a distal end of the catheter, and a second electrode spaced proximally from the first electrode and positioned on the catheter. It is to be noted that the functional language and introductory statement of intended use of claim 1, have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Svenson utilizes a mapping catheter as claimed by the applicant, Svenson is therefore capable of being inserted into a sheath, having a needle urged through, and being used as a dilator for performing a transseptal puncture and locating the fossa ovalis. In addition nothing prevents the catheter of Svenson from being performing these

functions. Therefore, they are capable of locating and penetrating the fossa ovalis and being used with a sheath and a needle.

8. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (U.S. 5,336,252). Cohen discloses (col. 5, lines 12-26) a guiding catheter, such that "a needle selectively deployable from the end of a flexible wire guide is fitted through the guiding catheter instrument channel and cuts an access hole through the pericardium into the pericardial space. The distal tip of the wire guide is inserted well into the pericardial space and deflected into a "J" shape to anchor the wire guide in the pericardial space. A dilator having a blunt, tapered end and a longitudinal bore slides over the wire guide and is advanced to the pericardial space to dilate the access hole. A flexible sheath slides over the dilator to form a channel when the dilator and guidewire are withdrawn. An electric lead is advanced through the sheath to penetrate the pericardial space and is secured there with anchors attached to the distal end of the lead." The examiner considers this to be a hollow lumen, a first electrode and a second electrode; wherein the catheter is inserted into a sheath for a transseptal puncture; a transseptal needle is urged through the lumen until the tip of the needle protrudes beyond the distal end of the catheter; a distal end of the catheter used as an electrophysiology mapping catheter for locating the fossa ovalis; and a dilator suitable for penetrating the fossa ovalis during a transseptal puncture procedure by urging the catheter over the needle.

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9. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al (U.S. 2002/0161422). Swanson discloses (par. 0124; Figures 1 and 2A) a probe (10), which includes "a flexible catheter tube (12) with a proximal end and a distal end (16). The proximal end has an attached handle (18). The multiple electrode structure (20) is attached to the distal end of the catheter tube." The examiner considers this to be a hollow lumen, a first electrode and a second electrode; the electrodes of Figure 2A to show a distal electrode with an electrode proximally spaced from the distal electrode. Swanson further discloses, (par. 0243) "a transeptal approach will most likely be used to create left atrial lesions. In a transeptal approach, an introducing sheath is inserted into the right atrium through the use of a dilator. Once the dilator/sheath combination is placed near the fossa ovalis under fluoroscopic guidance, a needle is inserted through the dilator and is advanced through the fossa ovalis. Once the needle has been confirmed to reside in the left atrium by fluoroscopic observation of radiopaque contrast material injected through the needle lumen, the dilator/sheath combination is advanced over the needle and into the left atrium. At this point, the dilator is removed leaving the sheath in the left atrium." The examiner considers this to be a catheter that is inserted into a sheath for a transseptal puncture; a transseptal needle that is urged through the lumen until the tip of the needle protrudes beyond the distal end of the catheter; a distal end of the catheter used as an electrophysiology mapping catheter for locating the fossa ovalis; and a dilator suitable for penetrating the fossa ovalis during a transseptal puncture procedure by urging the catheter over the needle.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svenson et al (U.S. 5,409,008), Cohen (U.S. 5,336,252) or Swanson et al (U.S. 2002/0161422). Svenson, Cohen and Swanson all disclose the claimed invention except for the second electrode spaced from the first electrode by a distance of between about 2 and 4 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a spacing of 2 to 4 mm, since it has been held that discovering the optimum value of a result of effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svenson et al (U.S. 5,409,008) or Swanson et al (U.S. 2002/0161422). Svenson discloses (col. 4, lines 19-22) a mapping catheter such that "wires (21a-21c) connect from the electrodes (42, 44 and 46) are contained in the polymer sheath (24), and travel through the electrical junction (20) to the electrical connectors (22a-22c)." Swanson discloses, (par. 0126) "the electrode elements are electrically coupled to individual wires (not shown in FIG. 1, but which will be discussed in greater detail later) to conduct ablating energy to them. The wires from the structure (20) are passed in conventional fashion

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through a lumen in the catheter tube and into the handle, where they are electrically coupled to a connector (38; see FIG. 1). The connector plugs into a source of RF ablation energy.” The examiner considers this to be a first and second electrical lead in communication with the first and second electrodes; and first and second cables at the proximate end of the catheter, wherein the first and second cables are in electrical communication with the first and second electrical leads. Though neither of these discloses attaching the cables to a device for recording electrograms, nothing prevents these cables from doing so. Therefore, Svenson and Swanson’s inventions are fully capable of being attached to a device for recording electrograms.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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